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Easyspine®

PEDICLE SCREW SYSTEM

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PEDICLE SCREW SYSTEM

Designed by leading
spine surgeons,
Easyspine® features
a simplified surgical
technique
and adaptable implants
to accommodate
various pathologies.

Unique, pre-assembled screws
- Pre-assembled locking components - no risk of dropping parts or cross threading
- Integrated multiaxial connections

A new standard: the LDR flattened rod
- Variable stiffnesses with a constant diameter
- Protection safety stops
- All rods compatible with all screws

Mechanical optimization
- Reliable locking (flat-on-flat connection)
- Final locking torque 30-50% below other systems' requirements

Implant options for all pathologies
- Standard screw
- Alpha screw
- LP screw
- Pedicle hook
- Under laminar hook
- Lateral connector
- Cross connection
- Spacer

Sterility and traceability
- Sterile packaging

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CE 0459

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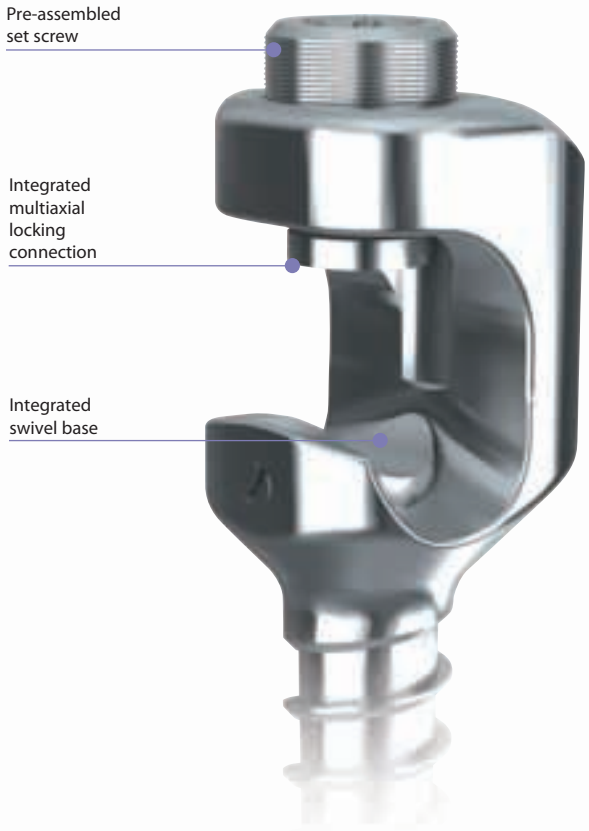
No assembly screws and hooks

Pre-assembled locking components

- No risk of cross threading set screws.
- No risk of dropping parts.

Integrated multiaxial joints

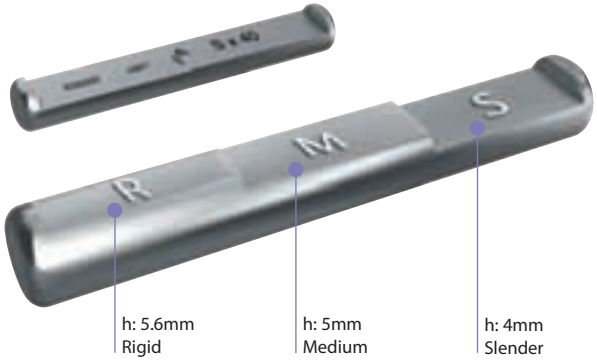
- Allows multiaxial range of motion.
- Adapts the screw to various pedicle trajectories.
- Directs the flattened part of the rod according to the desired lordotic curve.
- Allows for parallel distraction and compression.



A new standard: the LDR flattened rod

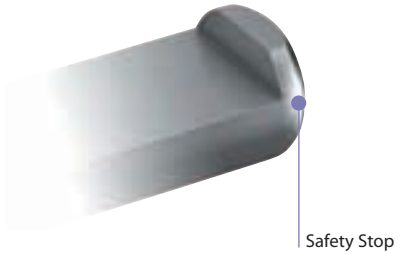
Variable stiffnesses with a constant diameter

Three rod heights with constant diameter (6mm) are available in order to obtain different construct rigidities, while using the same screws.



Protection safety stops

- The rod ends incorporate a 2mm stop to avoid any unintentional over-shooting of the rod at the superior and inferior screw assembly.
- The rod stops helps to protect the articular facet joints by allowing the rod end to be completely contained within the screw head, reducing the incidence of facet joint impingement.



Compatible with all screws

- All implants (screws and hooks) are interchangeable with all rods, whatever the stiffness.
- Rod choice can be made intraoperatively, once the screws or hooks are implanted.
- Take advantage of the low profile of the slender rods for the easiest rod loading.

Rotation control

The flattened rod helps prevent any rotation of the rod in the screw head during distraction, compression and scoliosis correction, as well as after final lock.

Restoration of lordosis

The flattened rod allows a visual check of the proper lordotic position in the screw heads.

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Mechanical optimization

Reliable flat on flat locking system

- Connection reliability is optimized by contact between two flat surfaces (flat rod matches flat-faced swivel joint), rather than the point or line contact of other systems.
- The final tightening torque is 30 to 50% below the requirements of other systems, minimizing the stress imposed on the overall construct and the spine[1].
- Pre-assembled set screws enable the tighter, stronger set screw thread pitch of 0.5mm:
  - Compare to the 1.25mm set screw pitch of competitive systems.
  - Increases the surface contact between the threads to ensure better long term lock reliability.

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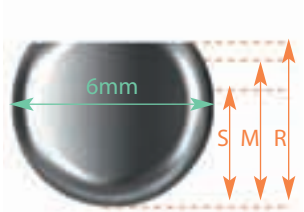
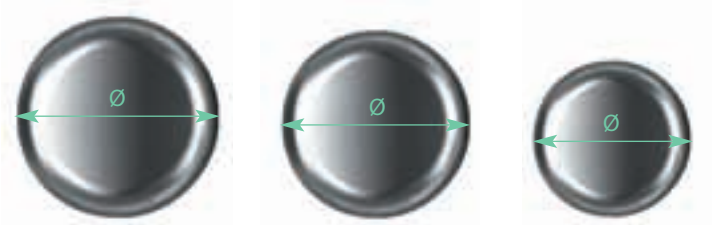
Contact surface

Point or line of points (Traditional system)

LDR Rods | **Conventional Rods**





"R" Rod:	h = **5.6**mm	=	Ø **5.9**mm
"M" Rod:	h = **5.0**mm	=	Ø **5.5**mm
"S" Rod:	h = **4.0**mm	=	Ø **4.6**mm

3 rigidities:
1 screw system

3 rigidities:
3 different systems

Comparison of stiffness between LDR rods and conventional round rods

Strong bony anchorage

- The Easyspine screw features a tapered core and constant outer thread diameter. Specially designed to:
  - Match anatomically tapered pedicles.
  - Maximize the diameter of the screw at the entry point of the pedicle (increasing the pullout strength).
  - Allow for height adjustments (stability is maintained by the outer threads at the screw's base).

Notable mechanical tests

Mechanical tests by an independent laboratory highlighted the following factors:

- The Easyspine multiaxial connection was able to withstand an axial load of 1400 N (slippage resistance test).
- Easyspine's maxiumum load without failure was in the better half of the competitors at 375 N (static multiaxial resistance test)[(2)].
- All tests were performed using a locking torque 30 to 50% below competitive systems and the smallest diameter screw of any competitor tested.

(1) Ralph Edward Stanford, FRACS, PhD, Andreas Herman Loefler, FRACS, Philip Mark Stanford, DipAppSci, and William R. Walsh, PhD, Multiaxial Pedicle Screw Designs: Static and Dynamic Mechanical Testing, SPINE Volume 29, Number 4, pp 367-375 (2004).

(2) Guy R. Fogel, MD, Charles A. Reitman, MD, Weiqiang Liu, PhD, and Stephen I. Esses, MD. Physical Characteristics of Polyaxial-headed Pedicle Screws and Biomechanical Comparison of Load with their Failure. SPINE Volume 28, Number 5, pp 470-473 (2003).

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Combine implants to fit the pathology

Alpha screw

- The multiaxial design allows for 20° of angulation in all directions; 40° total.
- Combines the mechanical resistance of a monoaxial screw with the advantages of a polyaxial screw.
- Allows for parallel distraction.

Standard screw

- Multiaxial locking ball joint allows for 20° of motion in a medial-lateral direction.
- Monoaxial screw designed for strength.

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PEDICLE SCREW SYSTEM

Combine implants to fit the pathology

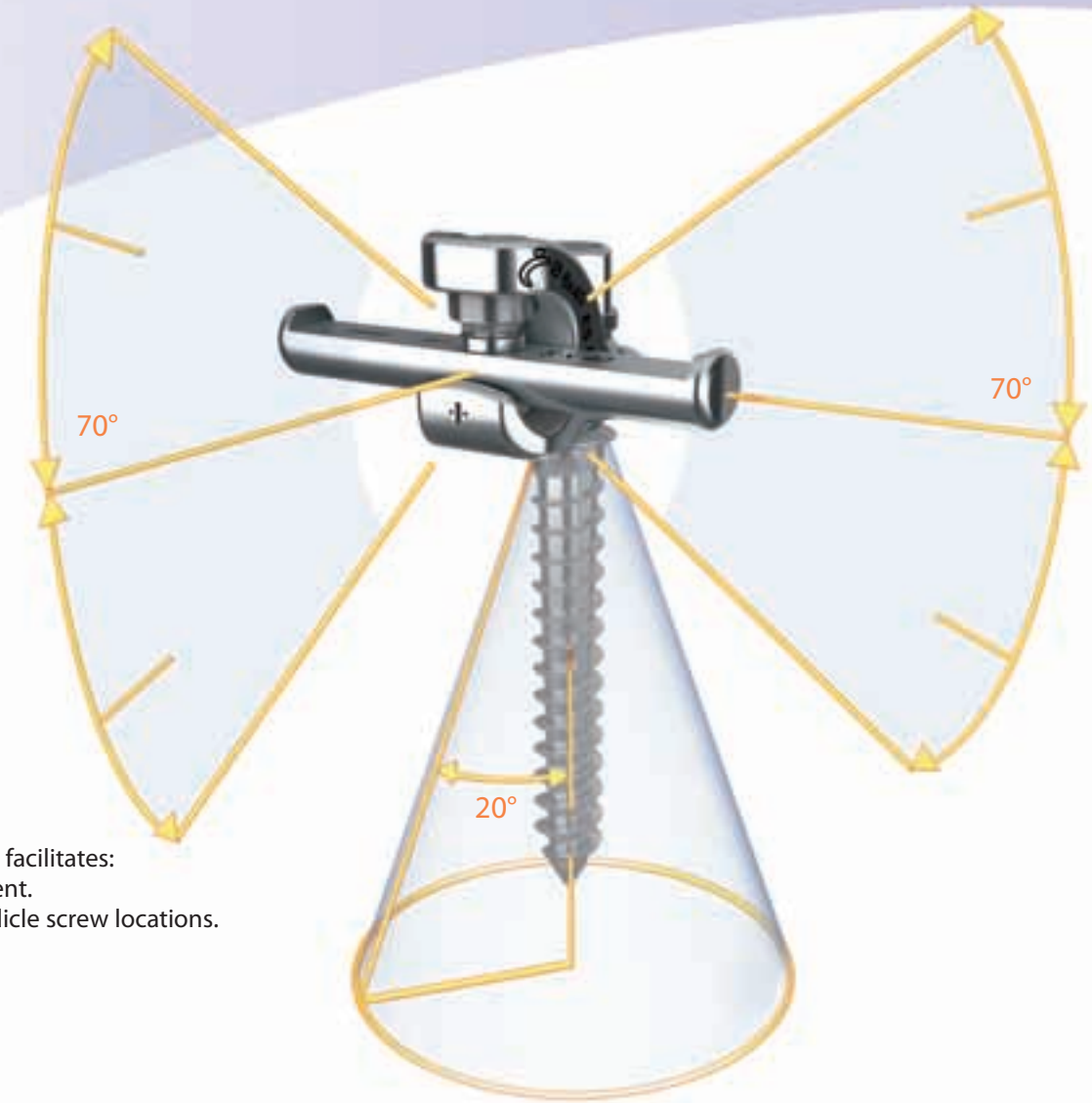
LP screw

Built-in offset

10mm of built-in offset facilitates:
- Lateral screw placement.
- The staggering of pedicle screw locations.
- Rod insertion.

70° of motion

- Screw allows 20° of movement in a 360° range
- Duel connection design allows for 70° of total head motion due to the:
  - Polyaxial component: the screw head to screw shaft connection.
  - Multiaxial component: the screw head to rod connection.



Independent movement shown

Unique spondylolisthesis reduction capabilities

Simplifies spondylolisthesis reduction with minimal instrumentation.

Independent component locking

Each multiaxial component locks independently, allowing:

- Greater control over reduction maneuvers.
- Pre-assembly away from the bone.

1. Independent locking of the screw head to the screw stem using the lock nut.

2. Independent locking of the rod in the screw head using the set screw.

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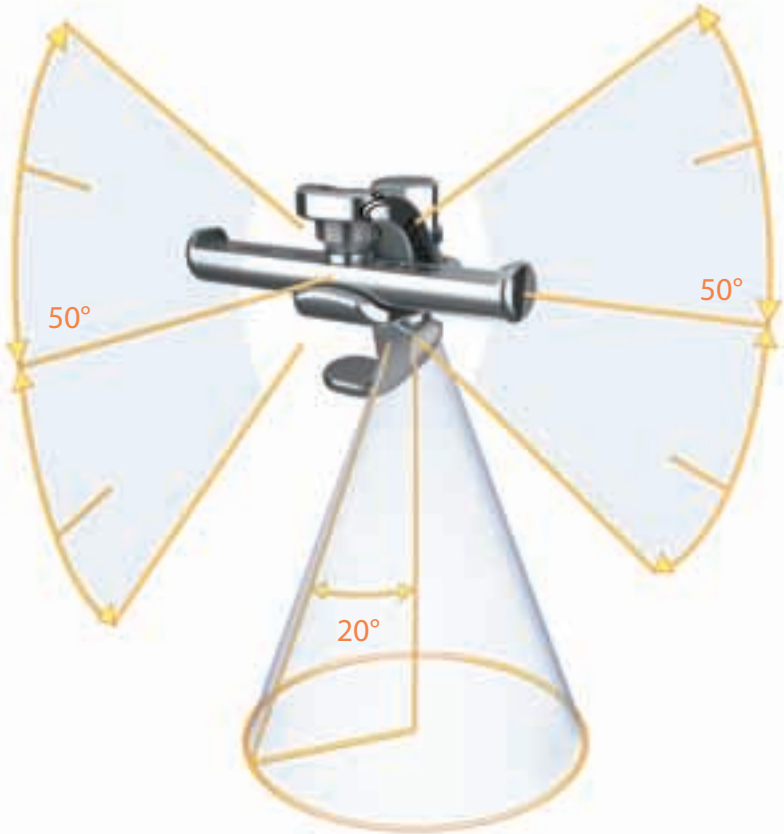
Combine implants to fit the pathology

Pedicle hook

- Multiaxial locking ball joint allows for 20° of angulation, 40° total.
- Designed for use in the thoracic region, T11 and superior.
- Right and left hook shapes available.

Under laminar hook

- Similar to the LP screw:
  - The duel connection design allows for 50° of total motion due to a polyaxial component (the head to hook connection) and the multiaxial component (the head to rod connection).
  - Hook allows 20° of movement in a 360° range
  - 10mm of built-in offset facilitates flexible hook placement.
- Designed for use in the lumbar region as an angled offset hook.
- Right and left hook shapes available.



Independent movement shown

Lateral connector

- Designed for use with the Alpha screw.
- Provides an adjustable offset distance of 13-24mm.
- Incorporates the same multiaxial connection used in the Standard screw.

Cross connection

Use in either compression or distraction.

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Sterility and traceability

LDR is the first spine company to guarantee the absolute traceability of its entire product range, due to our sterile packaging and lot numbering system.

Sterilization

All implants are double packaged in one blister pack and one vacuum packed plastic bag with sterilization control stickers.

Absolute traceability

Each implant is absolutely traceable from the initial manufacturing step to final implantation.

Product quality assurance

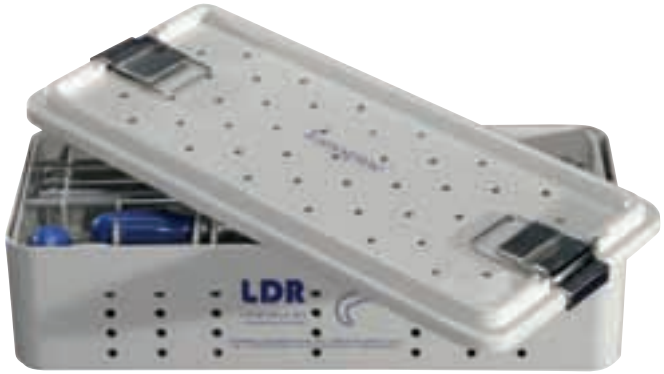
Sterile packaging ensures the implant is delivered to the surgical field in its original condition.

Optimized management

- Sterile packaging of implants allows immediate usage without any additional time or money required for sterile processing.
- **Easyrack™** "sterile implant distribution system" ensures a clean visual display and reliable management of implants in the operating room.

Instruments: A compact system

- Designed by and for spine surgeons.
- Simple and functional instrumentation help assure a reproducible technique.
- Full compatibility between all screws and all rods provides the same surgical options of typical pedicle screw systems, yet require only a third of the inventory.



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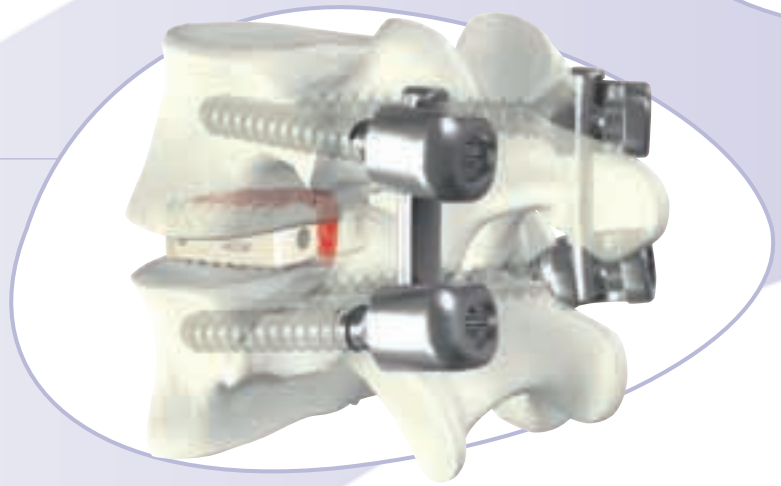
Degenerative Disc Disease

- Integrated locking mechanisms and pre-assembled multiaxial joints simplify construct assembly



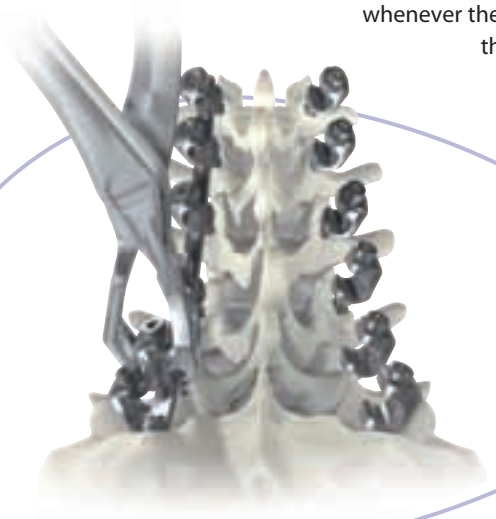
Dynamic Fusion

- The slender rod allows load sharing through the interbody device without compromising stability

Easyspine Pathology Map

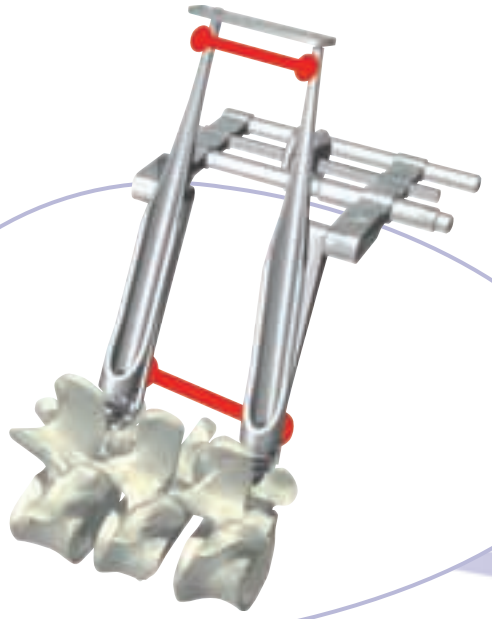
Spondylolisthesis

- The LP screw allows reduction of any grade spondylolisthesis and can be stopped whenever the surgeon achieves the desired position



Scoliosis

- The sequential loading capability enables controlled deformity correction



Trauma

- Smart instrumentation allows adjustment by the millimeter to control fracture reduction and preserve posterior height

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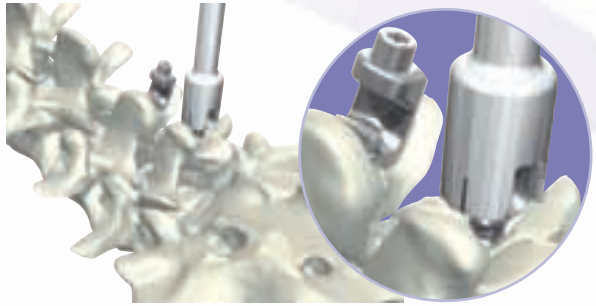
Easyspine and Degenerative Disc Disease

Designed for Ease of Use

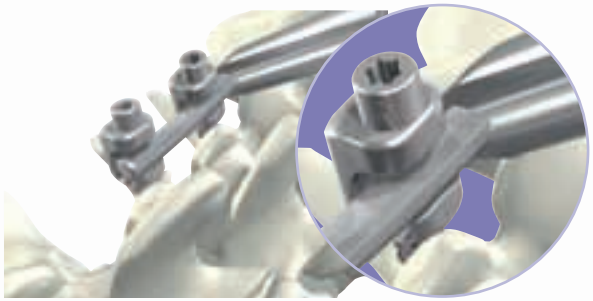
One level fusion

- No screw assembly required; multiaxial component and set screw are integrated.
- Requires only three instruments and three steps.
- Quick, especially when compared to competitive systems that require extra steps for locking and screw assembly.

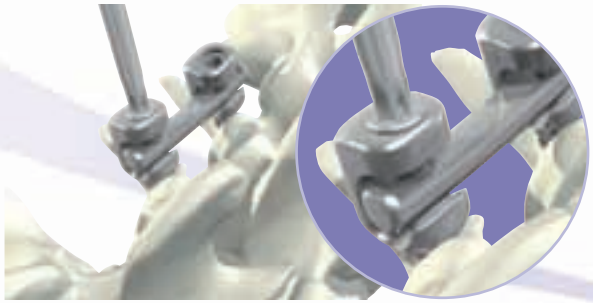
1. Implant screws with Screw Holder



2. Set rod in place with Rod Holder



3. Lock set screws with Screwdriver



Two or more levels of fusion

- Only four steps and four instruments are required (add the Rod Inserter as needed).
- An LP screw can be used at anatomically lateral L5.

Easyspine's Direct Design Benefits to Lumbar and Thoracic Fusion

Easyspine's design made key improvements when compared to a standard pedicle system to simplify a basic fusion case.

Screws

Integrated multiaxial locking mechanism

- No assembly required.
- Pre-assembled locking components and integrated multiaxial joints eliminate the risk of cross threading and require no additional instruments.
- Allows sequential rod loading.

Monoaxial design with polyaxial capabilities

- Combines the mechanical resistance of a monoaxial screw with the range of a polyaxial screw.
- Provides efficient and controlled compression and distraction.

Rods

Unique flat design

- Locking is optimized by contact between two flat surfaces.
- Safety stops protect against facet joint impingement by containing the rod end inside of the screw head.
- Flattened rod allows a visual check of the proper lordotic position in the screw heads.
- Flattened rod also helps prevent any rotation of the rod in the screw head during distraction and compression, as well as after final lock.

Modular rigidity

- Constant 6mm rod diameter available in three heights provides variable construct rigidity (S, M and R).
- All screws are compatible with all rods - no additional implants required.
- Select rod rigidity intraoperatively after screw positioning.

System

An implant for all pathologies

- Three screw options: Standard, Alpha and LP.
- Range of motion varies by screw: 20° medial-lateral, 40° of total motion and 70° of total motion.
- Use screws in any combination.

Post-Op X-Ray: Lateral View

Post-Op X-Ray: AP View

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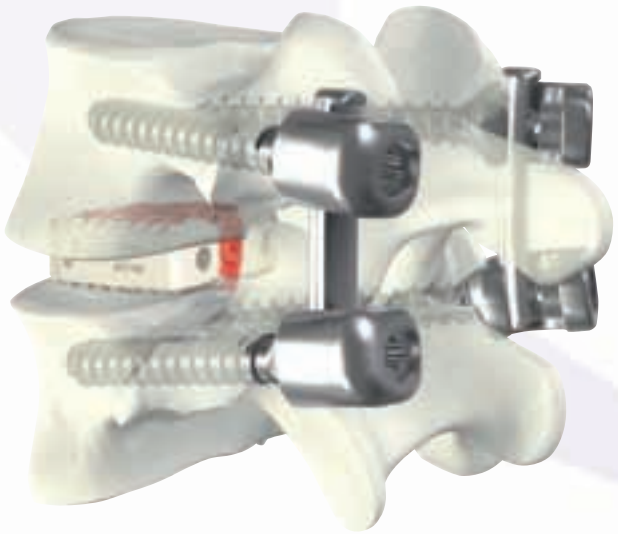
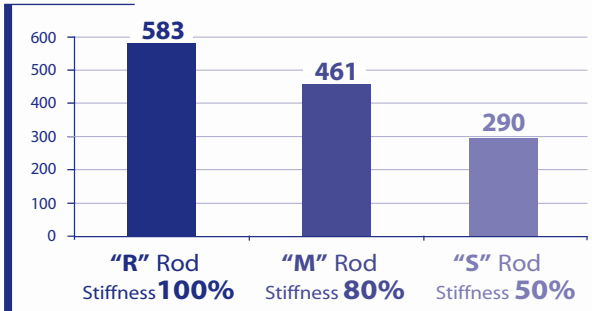
Easyspine and Dynamic Fusion

Slender Rods Improve Graft Loading



- Use an Easyspine slender rod with an ROI (PLIF), ROI-T (TLIF) or ROI-A (ALIF) to create a complete 360° solution.
- The slender rod is designed to improve the chance of fusion by continuing to load the graft in the fused areas, i.e., Wolfe's Law, "Bone responds to stress".
- The slender rod allows load sharing on the interbody device without compromising the stability of the spine.
- Revision to a stiffer construct is possible without removing any pedicle screws by swapping the slender rod (S) to a rigid (R) or medium (M).
- Rod rigidity can be selected intraoperatively after screw positioning.



RESULTS:

The Easyspine rods (R, M, S) are roughly equivalent to traditional round rods that are 5.9mm, 5.5mm and 4.6mm.

Elastic Limit for LDR Rods (Newtons)

Easyspine's Direct Design Benefits to Dynamic Fusion

Easyspine's slender rod creates the unique capability of dynamic fusion; load sharing with an interbody device to potentially improve and accelerate the rate of fusion.

Rods

Slender option

- The 4mm height of the slender rod decreases the rigidity in the anterior-posterior plane compared to the M (5mm) and R (5.6mm) rods.
- The 6mm diameter of the slender rod is the same as the M & R rods, providing the same rigidity during lateral bending (see chart page 7).
- Compared to a competitor's round rod, the low profile of the slender rod simplifies loading into the screw head.

Unique flat design

- Locking is optimized by contact between two flat surfaces.
- Safety stops protect against facet joint impingement by containing the rod end inside of the screw head.
- Flattened rod allows a visual check of the proper lordotic position in the screw heads.
- Flattened rod also helps prevent any rotation of the rod in the screw head during distraction and compression, as well as after final lock.

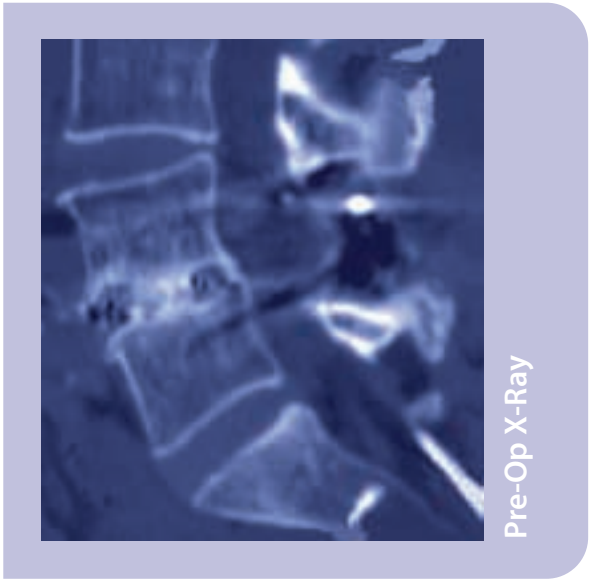
Screws

Integrated multiaxial locking mechanism

- No assembly required.
- Pre-assembled locking components and integrated multiaxial joints eliminate the risk of cross threading and require no additional instruments.
- Allows sequential rod loading.

Monoaxial design with polyaxial capabilities

- Combines the mechanical resistance of a monoaxial screw with the range of a polyaxial screw.
- Provides efficient and controlled compression and distraction.



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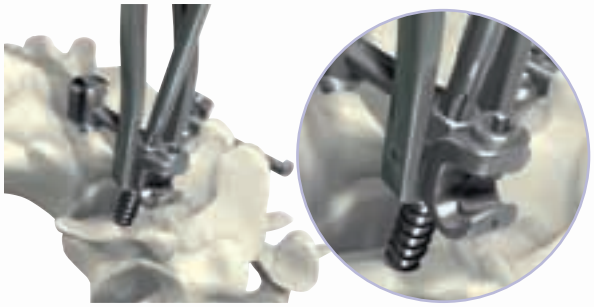
Easyspine and Spondylolisthesis Reduction

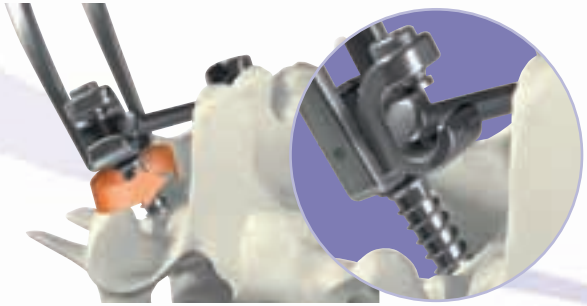
LP Screw: Restoring Sagittal Balance

- Use the LP screw to reduce any grade spondylolisthesis. The reduction can be adjusted and stopped whenever the surgeon has achieved the desired reduction amount.
- The LP screw achieves reduction by driving the screw into the vertebral body, increasing bony contact and decreasing the risk of screw pullout.
- The LP head can still be moved to adjust to the rod's lordotic curve before final lock.
- Only two additional instruments are needed to complete a reduction.

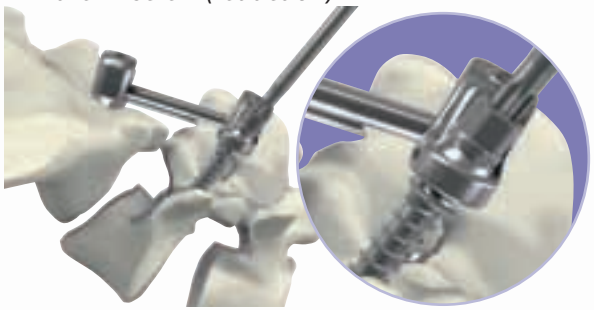
1. Insert LP screw



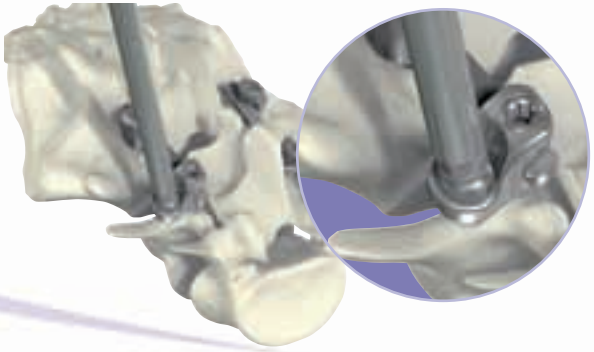
2. Rotate LP head to fully engage the flat rod



3. Pre-tighten the set screw; then drive in the LP screw (reduction)



4. Final locking of both set screw and nut



Easyspine's Direct Design Benefits to Spondylolisthesis

The LP screw, using the rod as a stable starting point, pulls the vertebral body posterior as the screw drives into the bone. This design allows flexible reduction amounts, based on anatomic requirements.

LP Screw

Built-in offset

10mm of built-in offset facilitates:
- Lateral screw placement.
- The staggering of pedicle screw locations.
- Rod insertion.

Independent component locking

- Each multiaxial component locks independently; locking the rod is independent of reduction.
- Reduction can be stopped at anytime and adjusted from 0 to 100%.
- Bony reduction is obtained by driving the screw into the vertebra.

Rods

Unique flat design

- Locking is optimized by contact between two flat surfaces.
- Flattened rod helps prevent any rotation of the rod in the screw head during final lock, as well as during distraction and compression.

Simple Instrumentation

- Only two additional instruments required.
- Simple, reproducible technique generates true reduction.

Pre-Op X-Ray

Post-Op X-Ray

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Easyspine and Scoliosis

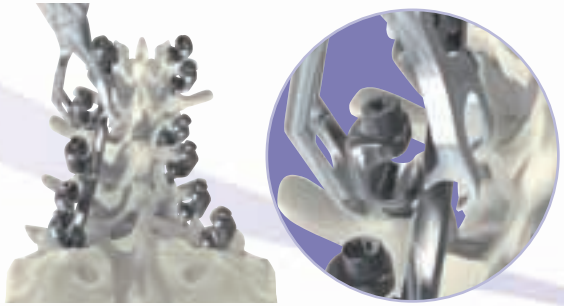
Easyspine Simplifies Scoliosis Reduction

Easyspine allows:

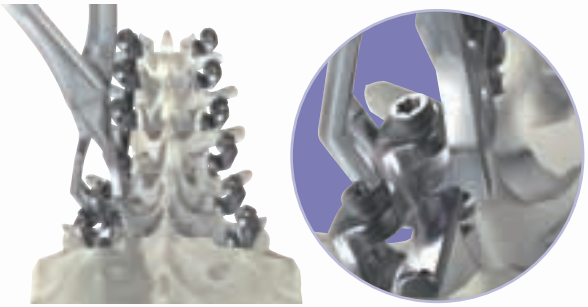
- One plane rod bending: lordotic and kyphotic. No coronal bend is needed.
- Sequential rod loading in each screw.
- Sequential rotation of the vertebra (rather than attempting one large rotational move) to achieve a high quality reduction.

1. Insert screws

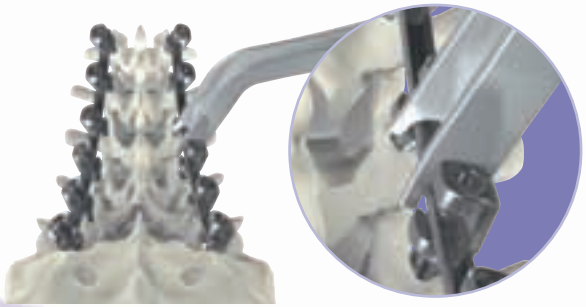
2. Insert rod in 1 or 2 screws



3. Sequentially load rod, screw by screw



4. Compression or distraction



Easyspine's Direct Design Benefits to Scoliosis

Easyspine improves scoliosis reduction by using a new sequential and transitional reduction technique. The goal: to restore the spine's sagittal balance through a three dimensional reduction, vertebra by vertebra. No one step de-rotation required and no obligation to load the rod simultaneously in all the screws.

Rods

Unique flat design

- Once one screw is loaded with a rod, the flat surface maintains the proper plane and provides a reference point for the next reduction step.
- The flattened rod allows a visual check of the proper lordotic and sagittal position in the screw heads.
- Flattened rod helps prevent any rotation of the rod in the screw head during final lock, as well as during distraction and compression.
- Locking is optimized by contact between two flat surfaces.

Simple Instrumentation

Rod Inserter

- Provides a tactical feel, helping to control the reduction and reduce the risk of pedicle breakage.
- Also provides rotation reduction control.

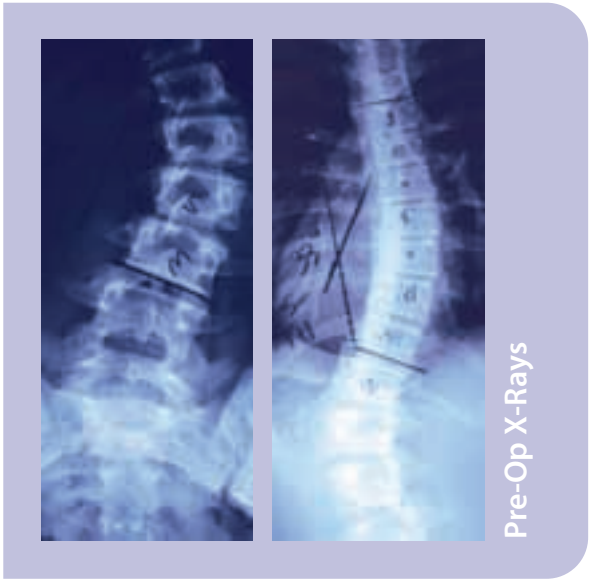
Screws

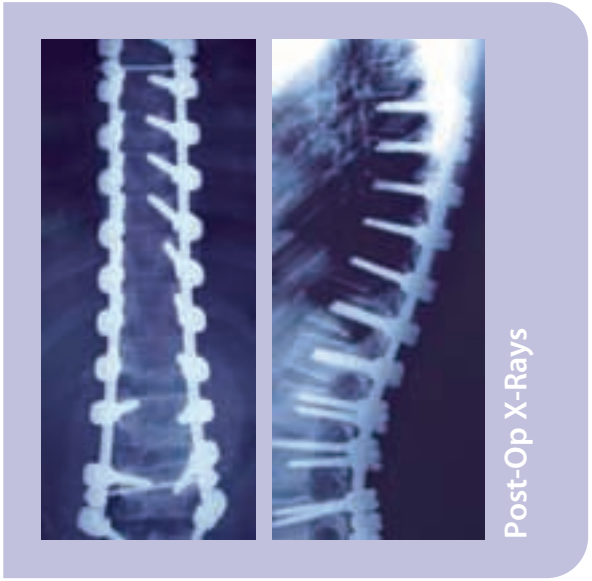
Side loading

- No need to put the rod in all the screws at the same time.
- This sequential loading allows fine-tuned reduction control, vertebra by vertebra; eliminating the need to globally de-rotate.
- The rod is bent only on the sagittal plane to restore patient balance and is not bent to fit into the screws.

Integrated multiaxial locking mechanism

- No assembly required.
- Pre-assembled locking components and integrated multiaxial joints eliminate the risk of cross threading and require no additional instruments.
- Allows 20° of freedom of the rod inside the screw head in the frontal plane (Standard screw) and 40° in all directions (Alpha screw).





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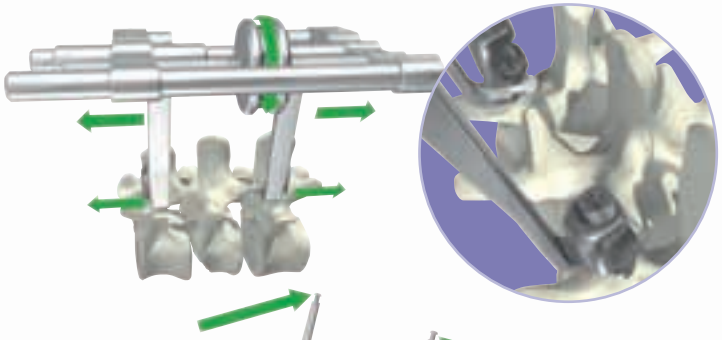
Easyspine and Trauma

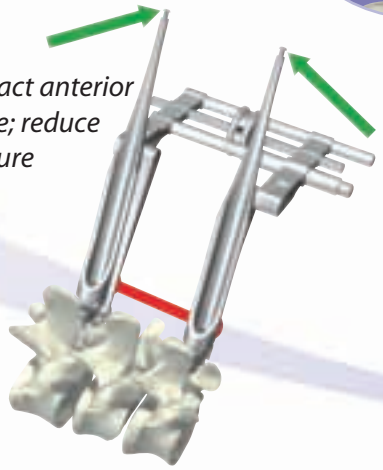
Easyspine Controls Fracture Reduction and Preserves Posterior Height

- The Alpha and Standard screws feature a monoaxial design with multiaxial capabilities perfect for distraction and compression.
- Pedicle and laminar hooks provide alternate multiaxial fixation.
- Well designed trauma instruments:
  - Allow alternating distraction and reduction.
  - Are self retaining.
  - Allow adjustment by the millimeter.

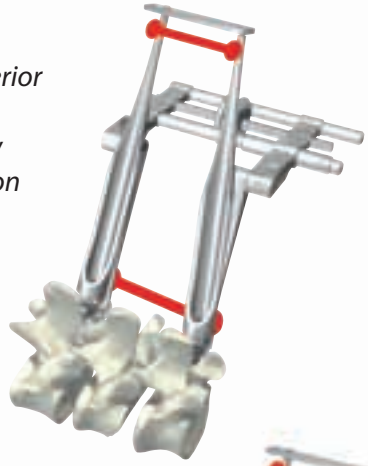
1. *Position Distractor Assembly and distract posterior space*



2. *Distract anterior space; reduce fracture*



3. *Lock anterior space and X-ray verification*



4. *Bend rod, insert and lock*

Easyspine's Direct Design Benefits to Trauma

Easyspine instrumentation offers excellent control of the fracture reduction with a reproducible surgical technique.

Simple Instrumentation

Smart design for trauma

- Only a few additional instruments are required to preserve posterior height and reduce the fracture.
- The instruments provide a controlled reduction, adjustable by the millimeter. At anytime, the reduction can be stopped and locked in place.
- The instruments are self stable and allow an intraoperative x-ray to validate the reduction.

Rods

Unique flat design

- Locking is optimized by contact between two flat surfaces.
- Flattened rod helps prevent any rotation of the rod in the screw head during final lock, as well as during distraction and compression.
- The flattened rod allows a visual check of the proper lordotic position in the screw heads.

Screws

Monoaxial design with integrated multiaxial locking mechanism

- Monoaxial screw design enables efficient and real compression or distraction between the vertebra.
- No assembly required
- Pre-assembled locking components and integrated multiaxial joints eliminate the risk of cross threading and require no additional instruments.
- Same range of implants available for trauma as for DDD.

Post-Op X-Ray: Lateral View

Post-Op X-Ray: AP View

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www.ldrmedical.com

France
Technopôle de l'Aube BP 2
10902 Troyes Cedex 9
France
+33 (0)3 25 82 32 63

China
Unit 08, Level 16, Building A,
Beijing Global Trade Center #36
North Third Ring Road
East, Dongcheng District,
Beijing, China, 100013
+86 10 58256655

Brazil
Rua Bela Vista, 77 - Centro
São Bernardo do Campo
CEP: 09715-030
São Paulo
Brazil
+55 11 43327755

United States
4030 West Braker Lane, Suite 360
Austin, Texas 78759
512.344.3333

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